

REMARKS

Status of the Claims

Claims 1-24 are currently pending in the application and subject to a Restriction Requirement. (See, Office Communication of July 29, 2008, at page 2, hereinafter, "Office Communication"). Applicants traverse the Restriction Requirement as set forth herein. Reconsideration is respectfully requested.

Restriction Requirement/Election of Species

Claims 1-24 are subject to a Restriction Requirement under 35 U.S.C. §§ 121 and 372 for reciting inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. (See, Office Communication, at page 2). Applicants traverse as hereinafter set forth.

For the purpose of examination of the present application, Applicants elect, with traverse, Group VI, Claims 12-14.

The Examiner states that the inventions of Groups I-X do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The Examiner states that the first claimed invention is anticipated by Deininger et al., *Acta Neuropath.*, 90:76-79, 1995, which allegedly discloses a method wherein in an increase in expression of BMP-5 serves to detect a lesion associated with multiple sclerosis.

However, it is respectfully noted that the invention of Group I encompasses both of presently pending claims 1 and 2. Present claim 2 is directed to "A method of evaluating the

degree of progress and/or the efficacy of treatment of proliferative diseases causing sclerosis, comprising measuring the expression of at least one substance selected from the group consisting of STAT3, phosphorylated STAT3, Smad1, phosphorylated Smad1, activin receptor-like kinase 1, activin receptor-like kinase 3 and bone morphogenetic proteins in a biological sample.” Deininger et al. is not believed to disclose this method. Particularly, Deininger et al. do not disclose a method of evaluating the degree of progress and/or efficacy of a treatment of sclerosis. That is, Deininger et al. do not anticipate the presently claimed invention because Deininger et al. do not disclose measurement of BMP proteins, followed by a treatment regiment, which is then followed by a second measurement of BMP proteins, to determine whether the expression of BMP proteins has changed after treatment, thereby allowing determination of progression of the disease which may be correlated to treatment. Anticipation requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (*See, In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1990), quoting *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Since the Examiner has failed to establish that any one reference anticipated the presently claimed invention, PCT Rule 13.1 mandates that the presently claimed invention not be restricted because the presently claimed invention in fact does encompass a single general inventive concept.

Therefore, reconsideration and withdrawal of the present restriction requirement are respectfully requested.

Species Election

In addition to the above Restriction Requirement, the Examiner has also imposed a Species Election on the presently claimed invention.

For the purposes of initiating examination, Applicants select, with traverse, species 2) Smad1 or phosphorylated Smad1 as a single species. At least claims 5-24 encompass the elected species.

Applicants understand that they must elect a single species for further prosecution. However, once the Examiner finds allowable subject matter based upon the single species elected, the Examiner is required to then expand the search to include a reasonable number of additional species. As provided in the M.P.E.P. at § 809.02 and stated by the Examiner:

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

According to MPEP §803, if the search and examination of an entire application can be made without a serious burden, the Examiner *must* examine it on the merits, even though it includes claims to independent or distinct inventions. Applicants believe that the search of four additional proteins, especially when such searches are easily made by simply using the name of the protein, would not amount to an undue burden on the Examiner.

Therefore, Applicants respectfully request that all of species 1-5 be searched simultaneously in the present application.

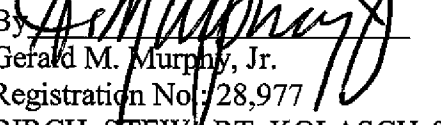
CONCLUSION

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,


By _____
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